



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2021-N-0387]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with recommended content of medical product communications that are consistent with the FDA-required labeling and recommendations for drug and device manufacturer communications with payors, formulary committees, and similar entities.

**DATES:** Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

**REGISTER]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2021-N-0387 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

## I. Medical Product Communications That Are Consistent With the FDA-Required Labeling--

### Questions and Answers

OMB Control Number 0910-0856--Extension

This information collection supports the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations that govern drug and device labeling and prescription drug and restricted device advertising. The FD&C Act specifies that a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular (section 502(a) (21 U.S.C. 352(a)) and that labeling may be considered misleading if it fails to reveal material facts about the product being promoted, including facts that are material in light of the representations made in a promotional piece (section 201(n) (21 U.S.C. 321(n))). Similarly, under sections 201(n) and 502(n) of the FD&C Act and FDA's implementing regulations (21 CFR 202.1(e)(5)(i) and (iii)), an advertisement for a prescription drug must not be false or misleading with respect to side effects, contraindications, or effectiveness, or fail to reveal material facts about the product being advertised, including facts that are material in light of the representations made in a promotional piece. The FD&C Act also specifies that restricted device advertisements must not be false or misleading (section 502(q)(1)) and must reveal facts that are material about the product being advertised (section 201(n)).

To assist respondents with the requirements drug and device labeling and prescription drug and restricted device advertising, we developed the guidance for industry entitled "Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers" (June 2018) (medical product communications guidance), available at <https://www.fda.gov/media/133619/download>. This medical product communications guidance includes recommendations that firms consider when developing "*consistent with the FDA-required labeling* (CFL)" presentations in their labeling and advertising materials to help ensure

the presentations are not false or misleading in violation of the FD&C Act and FDA's implementing regulations. The guidance also describes FDA's thinking when examining the consistency of a firm's product communications with that product's own FDA-required labeling.

As explained in the guidance, if a firm communicates information that is not contained in its product's FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use that is different from the use or uses for which the product is legally marketed. Establishing a product's intended uses is an element in establishing certain violations under the FD&C Act and Public Health Service Act. Firms' communications about their products that are consistent with the products' FDA-required labeling but that are false or misleading may subject a firm to enforcement action under the FD&C Act. Thus, the guidance not only describes FDA's thinking on communications that are consistent with the FDA-required labeling, but also provides general recommendations intended to help firms comply with requirements in the FD&C Act and FDA's implementing regulations for conveying information that is consistent with the FDA-required labeling in a truthful and non-misleading way. The medical product communications guidance recommends that firms accurately represent in the communications any study results or other data and information that are relied upon to support a firm's CFL promotional communication. Other recommendations include the clear and prominent disclosure of aspects of study design and methodology that are material for audiences to accurately interpret the information being presented (e.g., type of study, study objectives, product dosage and use regimens, control or controls used, patient population studied), as well as material limitations related to the study design, methodology, and results. Also, the guidance recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. In addition, the guidance recommends that firms disclose material contextual information from the FDA-required labeling in these

communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the CFL promotional communication.

The recommendations will help ensure that health care professional and consumer audiences receive truthful information about the benefits and risks of drugs and devices in firms' CFL promotional communications and that material contextual information is included in these communications so that audiences are not misled. Accurate information helps these audiences know whether drugs or devices may be appropriate for them or their patients and know what they can expect to experience when prescribing or using these products.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Information Collection Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling.	324	30	9,720	4	38,880

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Since our last request for OMB approval, we have made no adjustments to the currently approved burden estimate.

## II. Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities

OMB Control Number 0910-0857--Extension

This information collection also supports implementation of section 502(a) of the FD&C Act and applicable Agency regulations. Section 502(a)(1) of the FD&C Act provides that a drug or device is deemed to be misbranded “[i]f its labeling is false or misleading in any particular.” Under longstanding FDA practice and FDA’s statute and regulations, and under case law, *labeling* encompasses more than merely the label of the drug, but extends to other written, printed, or graphic matter “accompanying such article” (section 201(m) of the FD&C Act; see also 21 CFR 1.3(a)). Section 502(a) also includes a provision about communication of health

care economic information (HCEI) to payors through labeling or advertising. To assist respondents in this regard, we developed the guidance for industry and review staff entitled “Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities--Questions and Answers” (June 2018) (drug and device communications guidance), available at <https://www.fda.gov/media/133620/download>.

This drug and device communications guidance includes recommendations regarding information firms should include in HCEI for prescription drugs if they choose to disseminate such materials (HCEI materials) to payors, in accordance with section 502(a) of the FD&C Act. Specifically, if a manufacturer communicates HCEI for approved prescription drugs (including biological products that also meet the definition of *drug* under the FD&C Act and approved or cleared medical devices (collectively referred to as *medical products*)) to payors, FDA recommends that firms include in HCEI materials disseminated to payors information about: (1) various aspects of study design and methodology of an economic analysis (i.e., type of analysis, modeling technique, patient population, perspective or viewpoint, treatment comparator, time horizon, outcome measures, cost estimates, and assumptions); (2) factors that limit generalizability of an economic analysis; limitations to an economic analysis; and (3) sensitivity analyses, if applicable, to allow for informed decision making by payors.

Furthermore, FDA recommends that firms include other information when disseminating HCEI materials, as applicable, to provide a balanced and complete presentation. Such information includes a statement of the FDA-approved indication of the drug and a copy of the most current FDA-approved labeling. Under section 502(a) of the FD&C Act, firms must also include a conspicuous and prominent statement to describe any material differences between the HCEI and the FDA-approved labeling. HCEI materials should also disclose whether certain studies or data sources were omitted from an economic analysis and how the omission of those studies or data sources may alter the conclusions presented in the analysis. Moreover, FDA recommends that HCEI materials disclose important risk information associated with the



approved use of the drug, and pursuant to section 502(a) of the FD&C Act, HCEI materials must disclose any additional risk information related to assumptions that vary from the approved labeling. In addition, HCEI materials should disclose potential financial or affiliation biases to the extent reasonably known by firms at the time of dissemination.

The drug and device communications guidance provides similar recommendations for HCEI materials disseminated to payors about approved or cleared devices.

If firms choose to make communications to payors about unapproved products or unapproved uses of approved or cleared products, FDA recommends that firms include a clear statement with their communications that the product or use is not approved or cleared and that the safety or effectiveness of the product or use has not been established.

We estimate the burden of this collection of information as follows:

Table 2.-- Estimated Annual Third-Party Disclosure Burden <sup>1</sup>

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved prescription drugs.	430	10.465	4,500	20	90,000
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared devices.	236	10	2,360	20	47,200
Recommended information to be included when firms choose to disseminate information about unapproved products or unapproved uses of approved or cleared products.	717	2	1,434	0.5 (30 minutes)	717
Follow-up information to payors regarding previously communicated information about unapproved products or unapproved uses of approved or cleared products.	359	2	718	2	1,436
Total			9,012		139,353

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted the estimate of burden we associate with the information collection recommendations in the guidance to reflect an increase of 2,000 hours and 100 responses annually.

Dated: May 4, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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